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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,385	03/16/2001	Allen S. Laughon	WARF-0002	8778

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/810,385

Applicant(s)

LAUGHON, ALLEN S.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Request for Continued Examination*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2004 has been entered.

2. Claims 1-4 are pending.

Claims 1 and 2 have been amended.

Claims 1-4 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *New Grounds of Rejection*

#### *Claim Rejections - 35 USC § 112*

4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

In the previous amendment filed September 8, 2003 Applicant amended claims 1 and 2 to include the underlined recitation, "...complex of interacting proteins comprising a Smad protein, a Smad protein co-repressor...". Applicant has presently amended claims 1 and 2 to include the recitations, "containing interacting proteins comprising a Smad protein, a Smad protein co-repressor..." and "containing a Smad protein," respectively. While Applicant has deleted the phrases, "in the presence of a complex of" and "in the presence of" the claims still continue recite new matter.

Applicant has pointed out several passages within their specification where they believe "...the specification, when taken as a whole, clearly describes a complex inclusive of a Smad protein, a Smad protein co-repressor and a CtBP protein", see Remarks, page 5, first paragraph. The Examiner has reviewed the specified pages and lines, as well as the entire specification and has not found support for Applicant's contemplation of a method for identifying compounds comprising determining a first level of transcription detected in cells containing interacting proteins comprising a Smad protein, a Smad protein co-repressor. There continues not to be any support for the claimed method to include a *Smad protein* co-repressor in the assay comprising interacting proteins. Furthermore, this section of the specification does not support the contemplation of such a complex in the manner set forth in claim 1. Applicants have pointed out scientific observations, which can not be relied upon as support. Support should be based upon Applicant's own experimental design or original conception of an assay of record in the specification. Applicant is requested to pointedly express where support can be found or delete the new matter at which time the 102(a) rejection

set forth in the first action on the merits (FAOM), mailed May 6, 2003 may be reinstated.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 2 are vague and indefinite in the method steps. For instance, it is not clear what gene or genes are being transcribed or what molecule's transcription level should be detected. Claim 1 is indefinite in specifying the molecule whose transcription is repressed. Likewise, it is not clear from the method steps how the level of transcription is determined or detected. The claims reference that a comparison of levels of transcription is to be determined, however the method steps do not evidence how this step is implemented. It follows that the repression of transcription is induced by TGF-beta, activin or bone morphogenetic protein signaling, but there is no mention of what molecule or set of molecules is being repressed.

And while all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced. The method steps should at least include reagents necessary for the assay, a detection step in which the reaction products are quantitated or visualized and a correlation step describing how the results of

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the assay allows the determination of for example, the identification of compounds that directly interact with a Smad protein or a Smad protein co-repressor.

b. Claim 4 is vague and indefinite in the recitation "a homologue of dCtBP". It is not clear what type of molecule is deemed an analogue of dCtBP. Nor is it clear if the homologue is a duplicate, structurally equivalent and/or functionally equivalent to the wild type dCtBP. The metes and bounds of the claim cannot be determined.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however can normally be reached between the hours of 6:30 am to 4:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.

03 August 2004